

Ser. No. 10/693,328

REMARKS

This supplemental amendment is responsive to the Office Action mailed February 17, 2006 and to the Examiner Interview of Friday, July 14, 2006. Claims 1-31, 36-45 and 69-71 are under examination in the present action. Claims 32-35, 46-68, 72 and 73 have been withdrawn.

Applicants and their representatives once again thank the Examiner and her SPE for granting an interview to discuss the remaining issues in this case. The Examiner's helpful comments regarding claim language to advance the case were also appreciated.

During the interview, Applicants discussed the rejection of Claims 1-31, 36-45, and 69-71 under 35 U.S.C. §103(a) as unpatentable over Borody, international publication WO 89/05659 (hereinafter "Borody") in further view of Fordtran, international publication WO 87/00754 (hereinafter "Fordtran"), US Patent No. 5,458,890 issued to Williford et al., Stedman's Medical Dictionary (22nd Edition, 1972, page 737), and the Merck Index (Monograph 8723, 1996).

Applicants emphasized that bowel lavage solutions prior to Applicants' invention could be summarized into two categories:

- 1) large volume, *isosmotic* orthostatic lavage solutions typified by PEG lavage solutions; and
- 2) *super-hyperosmotic* solutions typified by sodium phosphate solutions.

Applicants pointed out that the art taught that the large volume isosmotic solutions typified by PEG lavage solutions needed to be isosmotic, *i.e.*, to have the same total osmolarity as the blood to keep water absorption and water secretion to a minimum. Applicants also discussed the patient compliance problems associated with these solutions, which require the patient to drink up to 4L of solution for effective treatment.

Applicants noted that art also taught *super-hyperosmotic* solutions of highly concentrated solutions of salts (for example sodium phosphate), which are *extremely hyperosmotic* (osmolarities of over 2000 mOsm/L) and result in a large amount of water being drawn from the bloodstream into the bowel, this recruited water from the patient's system being relied on to flush the colon. Applicants discussed the negative aspects of such solutions, particularly on patient blood electrolyte levels.

Applicants discussed their discovery, that cleansing solutions having an osmolarity of 300-700 mOsmol/kg were not only surprisingly effective at low volume, with good patient compliance, but also avoided the large secretion of water and consequent electrolytic imbalance caused by solutions having very high osmolarity.

Ser. No. 10/693,328

The previously submitted Rule 132 declaration of Dr. Borody, commenting on the teachings and beliefs in the art, *i.e.*, that practitioners were taught away from preparing solutions having osmolarity in the range recited in Applicants' original claims, namely, 300-700 mOsmol/kg, was also discussed with the Examiner.

At the conclusion of the interview, the Examiner suggested claim amendments to advance the case. Specifically, the Examiner noted that because of the location of the osmolarity recitation being positioned after the use of the term "optionally" in Claim 1, one interpretation of the claim was that the stated osmolarity was an optional limitation. Applicants have therefore amended Claim 1 herein as suggested by the Examiner to move the recitation of osmolarity to before the listing of ingredients. Support for the amendment is apparent from the original claim.

Additionally, the Examiner noted that Claims 36 and 69 did not contain the discussed osmolarity range limitation. Applicants have amended the claims to include the recitation. Support for the amendment is apparent from the original claims, e.g., Claim 1.

Applicants once again submit that the composition of the claims is in no way obvious to a person of ordinary skill in the art not having the benefit of Applicants' disclosure. Reconsideration and allowance are therefore respectfully requested.

Respectfully submitted,



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July 20, 2006

date



Michael R. Wesolowski